

James R. Condo (#005867)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, AZ 85004-2204
Telephone: (602) 382-6000
jcondo@swlaw.com
asheridan@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH LLP
Atlantic Station
201 17th Street, NW, Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

*Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA**

IN RE: Bard IVC Filters Products Liability
Litigation,

No. 2:15-MD-02641-DGC

**DEFENDANTS' RESPONSE IN
OPPOSITION TO PLAINTIFFS'
MOTION *IN LIMINE* NO. 5 TO
EXCLUDE EVIDENCE OF SIR
GUIDELINES**

(Assigned to the Honorable David G.
Campbell)

This Document Relates to:

Lisa Hyde, et al. v. C. R. Bard, Inc., et al.
CV-16-00893-PHX-DGC

1 Despite Plaintiffs' claims to the contrary, the SIR Guidelines are relevant to
2 Plaintiffs' statutory design defect claim, Bard's defense to that claim, Plaintiffs' negligent
3 design claim, and punitive damages.¹

4 Statutory Design Defect Claim: In 2011, Wisconsin enacted W.S.A.
5 895.047(1)(a)² which adopted the requirement of a reasonable alternative design, the
6 omission of which makes the product "not reasonably safe." Design of the product must
7 also "render[] the product unreasonably dangerous." *Id.* at 895.047(1)(b). The language
8 of the Wisconsin statute reflects the legislative adoption of the *Restatement (Third) of*
9 *Torts: Products Liability* section 2(b), which advances a risk-utility test for design defect
10 claims.³ As the Court knows, the SIR Guidelines have been published periodically since
11 2001 by the Society of Interventional Radiology, and they address the reported rates of
12 IVC filter complications generally, including fracture, tilt, migration, and penetration of
13 the IVC. Thus, the SIR Guidelines are relevant to evaluating what amounts to "not
14 reasonably safe" or "unreasonably dangerous" in light of reported adverse event rates of
15 other IVC filters and the notice to the medical community about these risks.

16 Moreover, although Wisconsin courts have not yet set forth the factors to consider
17 under its relatively newly adopted risk-utility test, other jurisdictions applying the same
18 *Restatement (Third) of Torts* risk-utility analysis have set forth such factors. For example,
19 as previously noted by this Court, Georgia's risk-utility analysis includes consideration of
20 "the user's knowledge of the product, publicity surrounding the danger, [...] as well as
21

22 ¹ This Court previously denied similar arguments to exclude this evidence based, in part,
23 on its relevance to consideration of design defect claims under a risk-utility analysis. (*See*
24 *Doc. 10258*, pp. 14-18.) The dismissal of Plaintiffs' failure-to-warn claims in this case
has no effect on the soundness of the Court's previous ruling.

25 ² While Plaintiffs correctly cite W.S.A. 895.047(1)(a) as the applicable law of Wisconsin,
26 Plaintiffs erroneously cite pre-2011 Wisconsin decisions which only applied the consumer
27 expectations test for design defect claims. Wisconsin's adoption of 895.047(1)(a)
effectively abrogated the decisions cited by Plaintiffs.

28 ³ Bard's trial brief sets out a more thorough analysis of Wisconsin's adoption of W.S.A.
895.047 and the *Restatement (Third) of Torts* risk-utility test.

common knowledge and the expectation of danger.” (*See* Doc. 10258, p. 15 (quoting *Banks*, 450 S.E.2d at 675 n.6).) Similarly, in Texas, application of the risk-utility test includes consideration of the user’s anticipated awareness of the dangers inherent to the product, general public knowledge of the obvious condition of the product, and the expectations of the ordinary consumer. *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009).⁴ In South Carolina, courts consider “the obviousness of danger.” *Branham v. Ford Motor Co.*, 390 S.C. 203, 218, 701 S.E.2d 5, 13 (2010). Under each of these factors, the “knowledge” of the general medical community concerning the inherent risks of IVC filters—as summarized in the SIR Guidelines—is relevant to consideration of the risk-utility factors.

Defense to Statutory Strict Liability Claim: W.S.A. section 895.047(3)(d) provides a complete defense to a strict liability design defect claim “if the damage was caused by an inherent characteristic of the product that would be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes the product.” *Id.* The SIR Guidelines reflect notice to the medical community about the risks attendant to all IVC filters and thus physicians’ long-standing knowledge of these risks, including levels of risk. Accordingly, the SIR Guidelines also are relevant to Bard’s defense under W.S.A. 895.047(3)(d).⁵

Negligent Design Claim: Bard’s knowledge of, and consultation with, the SIR’s analysis of the world-wide peer-reviewed medical literature as contained in the SIR Guidelines is relevant to whether Bard’s filters were in a “defective condition which would render such product unsafe” *Regent Ins. Co. v. Cincinnati Ins. Co.*, No. 14-C-

⁴ *See Restatement (Third) of Torts* § 2, cmt. f (discussing “the nature and strength of consumer expectations regarding the product”).

⁵ In its Order on Bard’s Motion for Summary Judgment (Doc. 12007, p. 12), the Court noted Bard’s reliance on the SIR Guidelines in support of its defense under W.S.A. 895.047(3)(d) and held that Plaintiffs’ challenge to the accuracy and applicability of the SIR Guidelines—a challenge Plaintiffs have raised again in their present motion—to be an issue for trial.

1 1434, 2015 WL 7681254, at *3 (E.D. Wis. Nov. 24, 2015) (quoting 3240 Wis. II-Civil).
 2 Moreover, the SIR Guidelines also inform about whether the performance of Bard's filters
 3 reflected conformance with industry customs and the state of the art. *Morden v. Cont'l*
 4 *AG*, 611 N.W.2d 659, 675 (Wis. 2000).

5 Punitive Damages: Because Plaintiffs are requesting that the jury consider Bard's
 6 design-related conduct in the context of the heightened standard required for punitive
 7 damages, the SIR Guidelines are relevant to punitive damages in the same way that they
 8 are relevant to Plaintiffs' negligent design claim. *State Farm Mut. Auto. Ins. Co. v.*
 9 *Campbell*, 538 U.S. 408, 422-23 (2003) (noting that due process, in the context of
 10 punitive damages demands that "[a] defendant should be punished for the conduct that
 11 harmed the plaintiff, not for being an unsavory individual or business").

12 Rule 403 Should Not Preclude Admissibility: Given the probative value of the SIR
 13 Guidelines to consideration of Plaintiffs' claims and Bard's defense in this case,
 14 Plaintiffs' argument for exclusion under Fed. R. Evid. 403 based on their disagreement
 15 that the SIR Guidelines set out "acceptable" complication rates for IVC filters is
 16 unavailing. As the Ninth Circuit has noted, "relevant evidence is inherently prejudicial;
 17 but it is only unfair prejudice, substantially outweighing probative value, which permits
 18 exclusion of relevant matter under Rule 403." *United States v. Hankey*, 203 F.3d 1160,
 19 1172 (9th Cir. 2000) (quoting *United States v. Mills*, 704 F.2d 1553, 1559 (11th
 20 Cir.1983)). The evidentiary admission of the SIR Guidelines is not rendered "unfair"
 21 merely because Plaintiffs disagree as to the intent of the SIR Guidelines. As this Court
 22 has previously held, Plaintiffs' challenge to the accuracy and applicability of the SIR
 23 Guidelines is an issue for trial. (*See* Doc. 12007, p. 12.) Consequently, Plaintiffs have
 24 failed to demonstrate that any alleged unfair prejudice substantially outweighs the
 25 probative value of the SIR Guidelines.

26 CONCLUSION

27 For these reasons, Bard respectfully requests that this Court deny Plaintiffs' Motion
 28 *in Limine* No. 5.

Nelson Mullins Riley & Scarborough

LLP
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

1 RESPECTFULLY SUBMITTED this 28th day of August, 2018.

2
3 By: s/Richard B. North, Jr.

4 Richard B. North, Jr.

5 Georgia Bar No. 545599

6 Matthew B. Lerner

7 Georgia Bar No. 446986

8 Nelson Mullins Riley & Scarborough LLP

9 201 17th Street, NW / Suite 1700

10 Atlanta, GA 30363

11 James R. Condo

12 One Arizona Center

13 400 E. Van Buren, Suite 1900

14 Phoenix, Arizona 85004-2202

15 **Attorneys for C. R. Bard, Inc. and Bard**
16 **Peripheral Vascular, Inc.**
17
18
19
20
21
22
23
24
25
26
27
28

CERTIFICATE OF SERVICE

I hereby certify that on August 28, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/ Richard B. North, Jr.

Nelson Mullins Riley & Scarborough

LLP
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000